REMARKS

Please, discard the previously submitted Response on the date of 01/03/2009 and replace this Supplementary Response.

With respect to the Objections of the Specification and Claims:

Regarding the objected Specification, the objections are revised by changing back to the original words and phrases or removing the new matter. Regarding the objected Claims, the objections are revised. Therefore, the objections of the Specification and the Claims are obviated by the above Specification and Claim Amendments.

With respect to the claim rejections under 35 U.S.C. 112 – first and second Paragraphs:

The ground rejections of claims 1 to 10 under 35 U.S.C. 112, first paragraph and second paragraph are obviated by the above Specification and Claim Amendments.

The examiner indicates that the description of the present specification is not enough to convey the claimed subject matter of the instant invention for the skilled person in the relevant art.

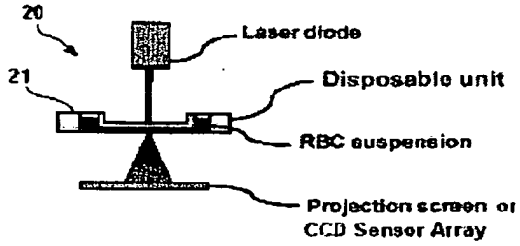
But, the inventor of the present invention asserts that the present specification has sufficiently described to carryout the claimed subject matter of the instant invention for the skilled person in the bio-medical art (blood testing technology).

However, the inventor will explain the instant invention in great detail for "measuring of the blood cell deformation, calculating the blood cell deformability, the variation of the shearing force (shear stress) according to the blood cell deformation based on time data received from the pressure gauge, and the images captured by the image capturing unit."

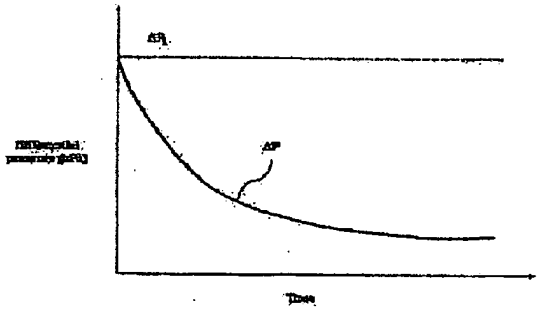
For better understanding, a process of the blood testing is presented as follows: a blood sample taken from a patient is diluted with the buffer solution to be a mixing ratio of

100:1 or 200:1 for testing.

(1) A blood test starts by placing a droplet of the diluted blood sample (0.5m*l*) in a blood sample pot (21) of a blood test kit (20) as shown a figure below.



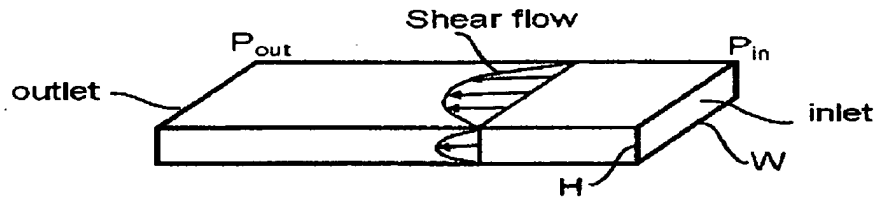
A switch is turned-on for operating a differential pressure generator (33) to generate a vacuum (negative) pressure in a slit channel (22). When the vacuum pressure applies to the waste blood pot (23), the blood sample will be penetrated into the slit channel (22). After completing the test, the blood sample is stored in the waste blood pot (23). The initial pressure difference (ΔP_i) is pre-set for operating. As the test progressing, the pressure variation is measured by the pressure gauge installed on the connecting tube between the waste blood pot (23) and the differential pressure generator (33). The operating vacuum pressure is exponentially varied as the pre-set initial pressure difference (ΔP_i) is approaching to the atmospheric pressure with the time elapse, $\Delta P(t) = (\Delta P_i) \exp(t)$, as shown in Fig. 6.



At this point, the blood cells in the diluted blood sample will be elongated as it flows through the slit channel due to the shearing force, which is caused by the resistance (friction)

against the walls of the slit channel (22).

Generally speaking, the flows of the diluted blood sample in the slit channel will be varied the velocities from the wall to the center of the tube, due to the resistance of the walls. This is a "shear flow," which is well known natural phenomenon of the fluid dynamics. As shown in the below figure, the shear flow is affected by the pressure difference (ΔP) of the inlet and the outlet, the viscosity of the fluid and the resistance of the wall.



The blood cells in the diluted blood sample would be elongated due to the shear forces in the slit channel (22). The shape and degree of the elongation of the blood cell are different depending on the patient's health condition, affected diseases, age and gender. This fact is also well known characteristics of the blood cell in the bio-medical technology.

In the office action, the examiner indicated that "*the applicant has not demonstrated what the relationship between the pressure (vacuum pressure) variation, the viscosity of the blood sample and the resistance of the slit channel to arrive at a calculated pressure using this pre-calculated data as consistent preset conditions.*"

With respect to the above questions, the present invention has adopted and applied the basic concepts, which are the shear flow of the natural phenomenon of the fluid dynamics, and the characteristics of the blood cell elongation in the shear flow, for utilizing to the blood testing.

Furthermore, it is not necessary to demonstrate the relationships between the affecting factors of the shear flow and the equations for calculating the deformation of the blood cell, because it has involved the numerous mathematical derivations and the plenty of the

experiments with simulations, which are outside scope of the instant invention.

However, the present specification has presented the empirical equations, which are the results of the mathematical derivations with the experiments, for calculating the blood cell deformability and shearing force.

A background of derivation of the empirical equation is briefly described as follows: regarding the viscosity of the blood sample, the viscosity of the blood is neglected because the blood sample is diluted with the buffer solution to be the mixing ratio of 100:1 or 200:1. The resistance (frictional factor) of the slit channel is determined through the simulations and experiments. Therefore, these factors of the viscosity and resistance are constant functions.

For simplifying the calculation, the affecting factors of the viscosity and the resistance are consistently pre-set as the non-variable functions for the empirical equation derivations. Through the numerous mathematical manipulation steps, the non-variable factors of viscosity and resistance are vanished in the empirical equations. Further, the pressure differential variation with time elapse, $\Delta P(t)$ can be pre-calculated or pre-determined with the experiment and the simulation. Then, the pre-calculated data of the pressure can be used instead of the instantly measured pressure data for calculating the shearing stress.

As the result, the empirical equations for calculating the blood cell deformability and shearing stress are introduced as a function of the pressure difference. Hereby, the empirical equations are presented for calculating the Deformability represented as a Deformation Index (DI) and the shear stress (τ) as shown in the instant Specification, pages 14 to 16.

Equation 1: $DI = (L-W)/(L+W)$ and Equation 6: $\tau = [\Delta P(t)\, H/L]/[(1+ 2H/W)]$.

Therefore, it is possible to input the consistent pre-set conditions, which are the initial pressure difference (ΔP_i), the viscosity of buffer solution and the resistance of slit channel, to the computer at a beginning of the blood testing by simply check-input a code number of the buffer solution and a model number of the test kit.

(3) The light emitting unit (10) emits the laser beams on the blood sample at the middle of slit channel (22) to project the images on the screen.

The examiner also indicated that *it is unclear how the image is captured "without projecting on the screen."*

The present invention employs a CCD sensor array to project the image instead of the conventional screen. The CCD sensor array has the multiple arrays (for example, 4 x 4), which forms a plurality of optical sensors in each array (for example, 2048 pixels). When the image is projected by the laser emitting unit, the projected image is captured by the optical sensors in the CCD sensor arrays to be interpreted and transformed to a digital signal for transmitting to the computer.

The deformation of the blood cell as the projected image is captured by the image capturing unit and analyzed by the ellipse curve-fitting computer software to measure a length (L) and a width (W) for calculating the deformability, which is represented by the Deformation Index (DI).

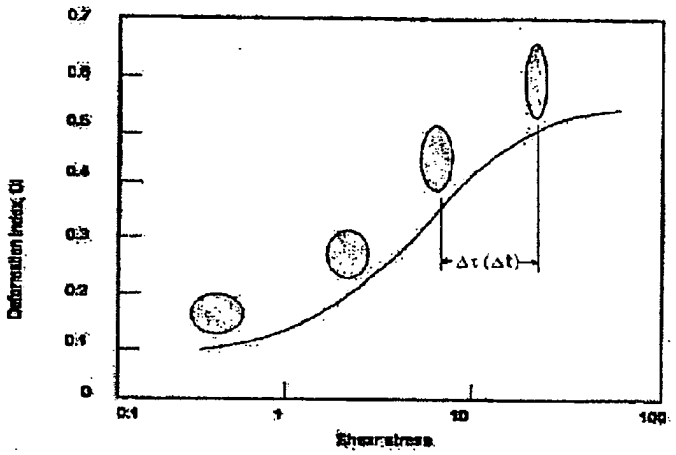
That is, the captured image is the actual blood cell deformation, and the calculated Deformation Index (DI) represents the deformability of the blood cell.

Once the Deformation Index (DI) and the shear stress (τ) are calculated through the computer programming, a graph is plotted with an ordinate as the Deformation Index (DI) (deformability) and an abscissa as the shearing stress, as shown figure below. The shearing stress (τ) is the function of the pressure variation with the time elapse.

The deformed blood cell has a tendency to resume the original shape (circular) with the time elapse as relief the shearing stress and the pressure difference. Thus, the deformed blood cell has a tendency to move from right to left along with the curve in the graph 7, i.e., the ellipse shaped blood cell tends to be the circular shaped blood cell as the time elapsed.

The smaller Deformation Index (DI) has the smaller deformability and the shape of

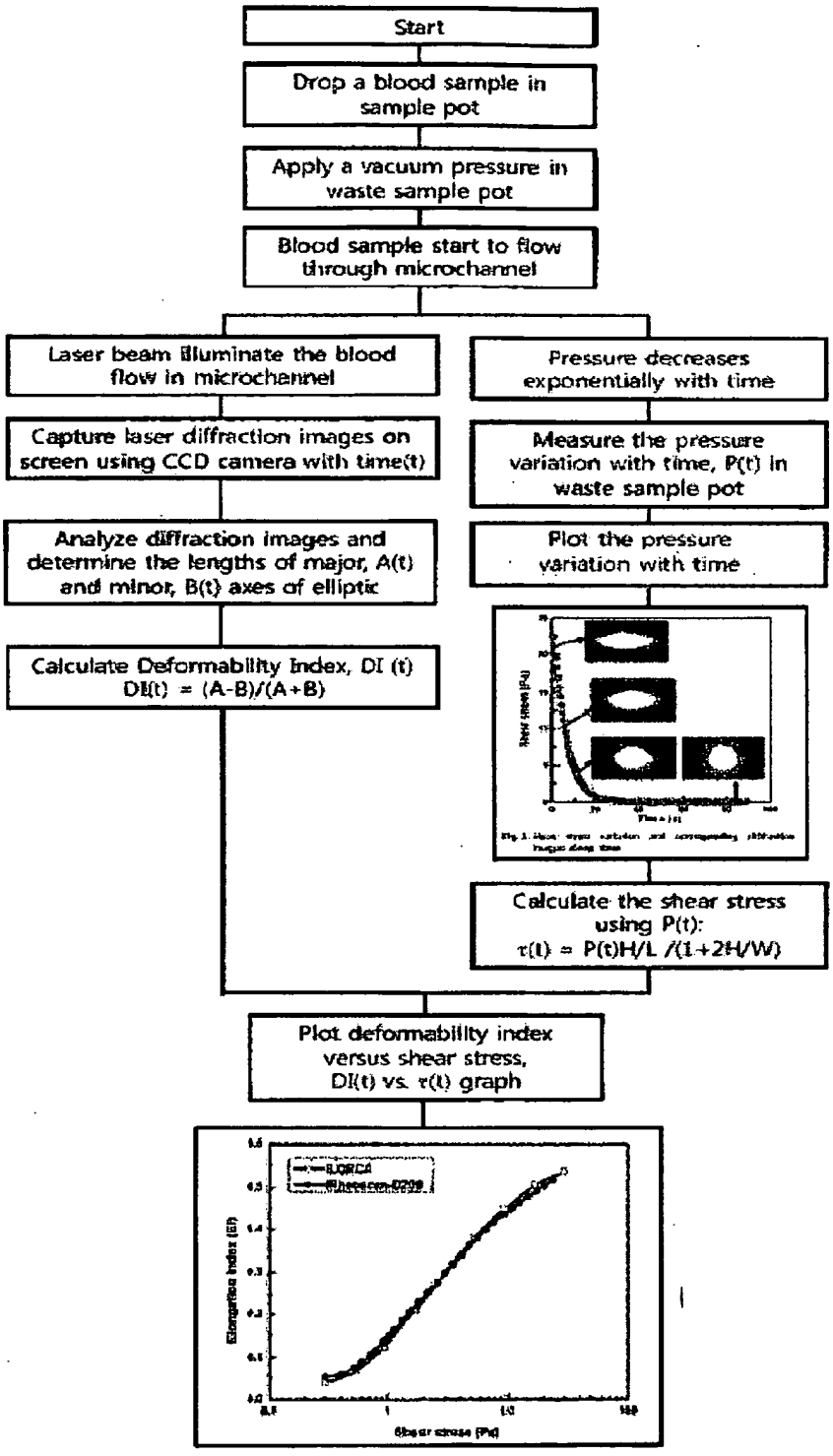
the blood cell tends to be closer to the circular shape, and vise versa. The larger shearing stress (τ) has the larger Deformation Index (DI) and the ellipse shape of the blood cell tends to be closer to the circular shape along with the curve of the Fig. 7, as the time elapsed.



Further, it is possible to calculate the unknown pressure variations with the known preset conditions and the pre-calculated data by reversely tracing the graphs.

For example, if a deformed shape of the blood cell with the known preset conditions is subject to identify, i.e., a code number of buffer solution (viscosity) and a model number of test kit (resistance) are known, but the pressure variation is not known, then the best matching deformed blood cell is searched via the ellipse curve-fitting computer software and read-in the shearing stress (τ) and the Deformation Index (DI) from the best matched graph, and the pressure variation is reversely calculated via the empirical equations.

(4) Hereinafter, a flow chart is presented to help easy understanding the process of the calculating deformability and shearing stress: a deformed image of the blood cell is captured by the image capturing unit (35) for calculating the deformability. The pressure difference (ΔP) is measured by the pressure gauge (34) for calculating the shear stress (τ) by the control unit (36). Then, a graph of the Deformation Index (DI) versus the Shear stress (τ) is plotted and displayed by the output unit (37).


Start
Drop a blood sample in sample pot
Apply a vacuum pressure in waste sample pot
Blood sample start to flow through microchannel
Laser beam illuminate the blood flow in microchannel
Capture laser diffraction images on screen using CCD camera with time(t)
Analyze diffraction images and determine the lengths of major, A(t) and minor, B(t) axes of elliptic
Calculate Deformability Index, DI (t)
DI(t) = (A-B)/(A+B)
Pressure decreases exponentially with time
Measure the pressure variation with time, P(t) in waste sample pot
Plot the pressure variation with time
Calculate the shear stress using P(t):
τ(t) = P(t)H/L /(1+2H/W)
Plot deformability index versus shear stress, DI(t) vs. τ(t) graph

Regarding a phrase of "according to pre-calculated data" (claim 1, line 20), the calculation of the shear force is distinctively divided to a shear stress (τ) as a function of the pressure variation (ΔP). Regarding the phrase of "such as" (claim 5, lines 2), it is revised to --which is one of--. A note is made that this phrase was revised to "such as," according to the paragraph 8 of the previous office action, mailed 03/13/2008. Regarding the rejected claim 8, a "screen" (claim 1, line 12) is revised to --means for projecting-- to make claim 8 dependable to the independent claim 1.

Further, the examiner indicated that claims 1 to 10 would be allowable if rewritten to overcome the rejections. Thank you for indicating the allowable claims 1 to 10.

Accordingly, the objections of the Specification and Claims are amended to overcome the 35 U.S.C. 112 first paragraph and second paragraph rejections. The above amendments are supported by the current Specification. No New Matter is entered.

Hereby, the above additional description is sufficient to clearly understand the present invention.

Therefore, the applicant believes the present application is now in allowance condition and early Notice of Allowance is respectively solicited.

Respectfully submitted

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